

REMARKS

The Office Action dated January 27, 2006 has been carefully considered. Claims 1-4, 11, and 12 are pending in the present application. Reconsideration of the present application in view of the following remarks is respectfully requested.

I. CLAIM REJECTION UNDER 35 U.S.C. § 102(e)

Claims 1-3 and 12 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,981,985 to Brown *et al.* ("Brown"). This rejection is respectfully traversed.

Independent claim 1 recites a medical device for delivering a biologically active material to a body tissue of a patient in need of treatment, wherein the medical device comprises a plurality of struts that form a plurality of openings; a plurality of non-structural elements integral with and projecting from the struts into the openings; and a coating comprising a biologically active material disposed on the struts and the non-structural elements. Claims 2, 3, and 12 depend from claim 1 and, thus, also include the recitations of claim 1.

Brown does not disclose or suggest "a plurality of non-structural elements integral with and projecting from the struts into the openings" and "a coating comprising a biologically active material disposed on the struts and the non-structural elements" as required by claim 1. Brown is directed to:

a stent having a reduced state and an expanded state and which is comprised of a plurality of interconnected struts. At least one strut is at least partially coated with a substance. The at least one strut has at least one bumper. The at least one bumper is constructed and arranged to prevent the substance on the at least one strut from being contacted by an adjacent component of the medical device when the stent is in the reduced state.

Abstract. Brown's bumpers are not non-structural elements that are able to adjust the distribution of the biologically active material in the body tissue so that the desired concentration-profile for the biologically active material released from the medical device into the body tissue can be achieved as described and claimed in the present application. *See, e.g.,* page 7, lines 30-34. Accordingly, Brown also does not disclose or suggest a coating comprising a biologically active material disposed on non-structural elements as required by claim 1.

Even if Brown's bumpers were non-structural elements (which they are not), Brown does not disclose that a *coating* is disposed on the bumpers. Brown states that:

. . .proper placement of substance 18 on to a selected portion or portions of the stent, such as a strut body 14, is ensured through the use of a mask 44 such as may be seen in FIG. 15. In use, placement of a mask 44 allows for any and all portions of the stent 10 to be masked leaving exposed a portion or portions 46 of the stent 10 which is to be coated. Through the use of a mask 44, the substance 18 may be placed very precisely. . . Preferably, if a given strut 12 is to be coated with a substance 18, the bumper 16 and any strut portion which may be engaged thereto is masked to ensure that substance 18 is only minimally contacted by the bumper 16, or not contacted at all.

Column 5, lines 21-37. The disclosure in Brown at column 5, lines 35-36, that “substance 18 is only minimally contacted by the bumper 16” does not teach or suggest that a coating is disposed on the bumper itself.

Therefore, Brown does not disclose or suggest non-structural elements and a coating comprising a biologically active material disposed on the non-structural elements as required by claim 1.

Accordingly, claim 1 and the claims depending therefrom are believed to be patentable over Brown. Accordingly, withdrawal of this rejection and allowance of claims 1-3 and 12 are respectfully requested.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

Claim 11 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Brown in view of U.S. Patent No. 6,506,437 to Harish *et al.* (“Harish”). This rejection is respectfully traversed.

Brown cannot be applied as a basis for an obviousness rejection. Pursuant to 35 U.S.C. § 103(c)(1) and M.P.E.P. § 706.02(k), a reference which qualifies as prior art only under one or more of subsections 35 U.S.C. § 102(e), (f), and (g) does not qualify as a prior art reference against an application if: (1) such application was pending on or after December 10, 2004; and (2) the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Brown was not published until after the present application was filed, and thus can only qualify as prior art under 35 U.S.C. § 102(e). The present application was pending on December 10, 2004. In addition, at the time the present invention was made, the inventors of Brown and the inventor of the present application were subject to an obligation to assign their respective inventions to Scimed Life Systems, Inc. Pursuant to this obligation, an Assignment from the inventors of the invention in Brown to Scimed Life Systems, Inc. was

recorded in the U.S. Patent and Trademark Office ("USPTO") on January 22, 2002, at Reel 012528, Frame 0448, and an Assignment from the inventor of the present invention to Scimed Life Systems, Inc. was recorded in the USPTO on April 8, 2002, at Reel 012780, Frame 0828. Thus, Brown does not qualify as prior art that can be used in 35 U.S.C. § 103(a) rejection.

Moreover, Harish does not disclose or suggest: (1) non-structural elements integral with and projecting from the struts into the openings; and (2) a coating comprising a biologically active material disposed on the struts and such non-structural elements, as recited in the present claims. Harish discloses a device that has depots formed in the outer surface thereof. (Col. 3, lines 32-33). Also, Harish discloses applying a composition including a therapeutic substance into the depots. (Col. 2, lines 19-20). However, the depots are not non-structural elements integral with and projecting from the strut into the openings. (*See, e.g.*, Figure 3B of present specification). The depots of Harish are not non-structural elements since they are formed from the removal or absence of material in the outer surface of the device. Such depots of Harish do not project from the struts into the openings formed by a plurality of struts as required by the present claims. Therefore, Harish does not disclose or suggest the presently claimed invention.

Accordingly, withdrawal of this rejection and allowance of claim 11 are respectfully requested.

III. ALLOWABLE SUBJECT MATTER


Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims. For the reasons discussed above, it is believed that claim 1 is patentable over the references cited herein. Thus, claim 4 which depends from claim 1 is also believed to be patentable. Accordingly, withdrawal of this objection and allowance of claim 4 is respectfully requested.

IV. CONCLUSION

Since all rejections to the claims are believed to be overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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